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MAY - 7 1998

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SmithKline Beecham Corporation
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939

Re: Patent Term Extension
Application for
U.S. Patent No. 5,004,758

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,004,758, which claims the human drug HYCAMTIN® (topotecan HCl) and methods of use of HYCAMTIN®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 786 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 786 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of March 20, 1998 (62 Fed. Reg. 13388). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,485 - 759) + 159 \\ &= 1,022 \text{ days}\end{aligned}$$

Since the regulatory review period began March 4, 1989, before the patent issued April 2, 1991), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From March 4, 1989 to April 2, 1991 is 759 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,022 days, would extend the patent from April 2, 2008 (35 U.S.C. § 154) to January 19, 2011, which is beyond the 14-year

limit (the approval date is May 28, 1996, thus the 14 year limit is May 28, 2010). The period of extension is thus limited to May 28, 2010, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, April 2, 2008, to and including May 28, 2010, or 786 days.

The limitations of 35 U.S.C. § 156 (g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,004,758
Granted:	April 2, 1991
Original Expiration Date ¹ :	April 2, 2008
Applicant:	Boehm et al.
Owner of Record:	SmithKline Beecham Corporation
Title:	Water Soluble Camptothecin Analogs Useful for Inhibiting the Growth of Animal Tumor Cells
Classification:	514/283
Product Trade Name:	HYCAMTIN® (topotecan HCl)
Term Extended:	786 days
Expiration Date of Extension:	May 28, 2010

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

¹Subject to the provisions of 35 U.S.C. § 41(b).

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520
2011 Crystal Drive
Arlington, VA

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.



Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: HYCAMTIN®
FDA Docket No.: 96E-0440